This guidance for industry represents the agency's current thinking on scale-up and post approval equipment changes for immediate release solid oral dosage forms regulated by CDER. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Persons with access to the Internet may obtain copies of ''SUPAC–IR: Immediate Release Solid Oral Dosage Forms—Manufacturing Equipment Addendum'' by using the World Wide Web (WWW) and going to ''http://www.fda.gov/cder/guidance/index.htm''.

Dated: October 14, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–27738 Filed 10-20-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for U.S. companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by contacting George Keller, Ph.D., Technology Licensing Specialist, at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057, ext. 246; fax: 301/402–0220; e-mail: KellerG@od.nih.gov. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Diagnostic Reagents and Vaccines for Multiple Genotypes of Hepatitis C Virus

J Bukh, RH Miller, RH Purcell (NIAID)
Serial Nos. 08/466,601 and 08/468,570 filed 06 Jun 95 (DIV of U.S. Patent 5,514,539 issued 07 May 96)

The invention describes the complete nucleotide and deduced amino acid sequences of the envelope 1 (E1) gene of 51 hepatitis C virus (HCV) isolates from around the world and the grouping of these isolates into twelve distinct HCV genotypes. More specifically, this invention relates to the oligonucleotides, peptides and recombinant proteins derived from the envelope 1 gene sequences of these isolates and to diagnostic methods and vaccines that employ these reagents.

Antigenic Protein of Borrelia Burgdorferi

WJ Simpson, TG Schwan (NIAID)
Serial No. 08/396,957 filed 01 Mar 95 (DIV of U.S. Patent 5,470,712 issued 28 Nov 95)

This patent application describes a 39 kDA protein (P39) that is species-specific and expressed by all North American and European *B. burgdorferi* isolates. The discovery includes the cloning and expression of the gene for P39 in *E. coli* and the use of P39 as a diagnostic antigen for the serodiagnosis of Lyme borreliosis. The P39 described in this invention report has been found not only to be species-specific, but reactive only with human Lyme borreliosis sera. This suggests that any patient's serum that is shown to react to P39, irrespective of the patient's clinical picture, can be diagnosed as having or having had Lyme borreliosis.

Versatile Reagent for Detecting Murine Leukemia Viruses

LH Evans, WJ Britt (NIAID)
Serial No. 08/046,352 filed 08 Apr 93

Monoclonal antibodies directed at the proteins of murine leukemia viruses (MuLVS) have some value as immunological reagents, but differ greatly in their applicability. The kit described in this invention uses a monoclonal antibody designated 83A25, which identifies almost all ecotropic, xenotropic, polytropic, and amphotropic MuLVs. It can be used in a wide variety of procedures, including focal immunofluorescence assays on live or fixed monolayers, immunoblotting, immunoprecipitation, immunohistochemical, and flow cytometric procedures. This kit overcomes some of the problems associated with prior methods, which may not effectively precipitate proteins or react in immunoblots, are not capable of detecting MuLVs belonging to all classes with a single reagent, and may not efficiently neutralize all MuLVs.

Dated: October 7, 1997.

Barbara M. McGarey, J.D.

Deputy Director, Office of Technology Transfer.

[FR Doc. 97–27864 Filed 10–20–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Allergy and Infectious Diseases Special Emphasis Panel (SEP) meeting:

Name of SEP: Therapeutic Strategies for Papillomavirus (Telephone Conference Call).

Date: October 29, 1997.

Time: 2:00 p.m. to Adjournment.

Place: Teleconference, 6003 Executive Boulevard, Solar Building, Room 1A1, Bethesda, MD 20892, (301) 402–0747.

Contact Person: Dr. Sayeed Quraishi, Scientific Review Adm., 6003 Executive Boulevard, Solar Bldg., Room 4C22, Bethesda, MD 20892, (301) 496–7465.

Purpose/Agenda: To evaluate contract proposals.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than 15 days prior to the meetings due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Programs Nos. 93.855, Immunology, Allergic and Immunologic Diseases Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health)